

**YU SHEN TANG CHINESE HERBAL MEDICINE, LLC.**

8855 E Valley Blvd, #B1, Rosemead, CA 91770 Tel: 626-286-0171 Fax: 626-286-0172

Office of Special Nutritionals (HFX-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

SEP 20 2004

September 6, 2004

**Notification Letter for Statement on  
Dietary Supplement**

Dear FDA officers:

I am the president of Yu Shen Tang Chinese Herbal Medicine, LLC, who is, among other things, a manufacturer and distributor of dietary supplements in California. I am writing as per Code of Federal Regulations, Volume 21, Part 101.93, to notify you that we have included statements on the label and in the labeling of one of our products. The following are the information required in this notification letter:

1. Statement of Purpose.

This is a letter to provide notification of a statement of nutritional support, including the exact wording that appears on the label and labeling for a dietary supplement.

2. Vendor Information:

Name, address, telephone and fax numbers of the manufacturer and distributor for mailing and other communication purposes, are as follows:

YU SHEN TANG CHINESE HERBAL MEDICINE, LLC.  
8855 E. Valley Blvd. #B1  
Rosemead, CA 91770  
Tel. 626-286-0171  
Fax: 626-286-0172

3. Product Identification:

The trade name of the product:

975 0162

LET

14624

89599

## Zhen Ge Jiang Tang Dan Capsules

The common and usual name of the product:

Zhen Ge Jiang Tang Dan

A label copy showing all information displayed and provided to consumers is attached

### 4. The text of the Structure/Function Statement.

**Dietary Supplement in assisting of building a balanced and healthy glucose metabolism**

### 5. Ingredient Statement

This product is a proprietary blend of herbal and other natural ingredients. The following is a complete list of dietary ingredients:

The ingredients are listed in the order of Common Name, Scientific Name in Brackets, Part used, Traditional Chinese Medicine Name in phonetic alphabet.

Mother-of-Pearl (*Pteria margaritifera*) shell (Zhen Zhu Mu)  
Gecko (*Gekko gecko*) lizard (Ge Jie)  
Dogwood (*Cornus officinalis*) fruit (Shan Zhu Yu)  
Chinese Yam (*Dioscorea opposita*) rhizome (Shan Yao)  
Prepared Rehmannia (*Rehmannia glutinosa*) root (Shu Di Huang)  
Wolfberry (*Lycium chinense*) fruit (Gou Qi Zi)  
Dodder (*Cuscuta chinensis*) seed (Tu Si Zi)  
Chinese angelica (*Angelica sinensis*) root (Dang Gui)  
Cinnamon (*Cinnamomum cassia*) bark (Rou Gui)  
Prepared Aconite (*Aconitum carmichaeli*) root (Fu Zi)  
Polygala (*Polygala tenuifolia*) root (Yuan Zhi)  
Ginseng (*Panax ginseng*) root (Ren Shen)  
Psoralea (*Psoralea corylifolia*) fruit (Bu Gu Zhi)  
Astragalus (*Astragalus membranaceus*) root (Huang Qi)  
Eucommia (*Eucommia ulmoides*) bark (Du Zhong)  
Hoelen (*Poria cocos*) sclerotium (Fu Shen)

### 6. Intended Use

This product is intended to be used for persons over the age of 18 who would like to have a balanced glucose metabolism and maintain blood glucose at a healthy level \*

Suggested use: Three capsules (1.5g) per dose, twice daily.

**Caution:** If taking prescription medication, consult your health professionals before use. Store at a dry place below 86° F ( 30° C), Keep this product and all drugs out of reach of children.

7. Statement of Affirmation:

We, as manufacture and distributor of the above mentioned product, affirm that we have substantiation that the structure/function statement (as shown in No. 4 above) made under 403(6)(r) of the federal Food, Drug and Cosmetic Act is truthful, not misleading, and scientifically valid and that the product does not present a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in the label or labeling.

8 Disclaimer:

At the end of each structure/function statement, there is an asterisk that refers to another asterisk placed adjacent to the disclaimer. The disclaimer is placed at the bottom of the same panel or, in adjacent with the structure/function statement. The disclaimer reads

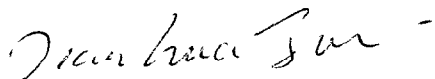
**These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.**

Should there be any question or comment, please contact the Vendor through the information in No. 2 above, or contact the preparer of this notification letter:

George Su  
Crosslinks International, Inc  
1800 Century Park East, Suite 600  
Los Angeles, CA 90067

Tel. (310)229-5748  
Fax. (310)388-1067  
E-mail: [crosslinks2000@aol.com](mailto:crosslinks2000@aol.com)

Sincerely,



Zou Jianhua  
President

Enclosures

## **Information on Label**

### **Zhen Ge Jiang Tang Dan Capsules**

**Dietary Supplement in assisting of building a balanced and healthy glucose metabolism\***

**Net Content: 500 mg x 90 capsules**

**This product is intended to be used for persons over the age of 18 who would like to have a balanced glucose metabolism and maintain blood glucose at a healthy level.\***

**Suggested Use: Three capsules (1.5g) per dose, twice daily.**

**Do not use if imprinted seal is broken or missing.**

**Caution: If taking prescription medication, consult your health professionals before use. Store at a dry place bellow 86<sup>0</sup> F ( 30<sup>0</sup> C), Keep this product and all drugs out of reach of children.**

**Expiration Date:**

**Manufactured by:  
Yu Shen Tang Chinese Herbal Medicine, LLC  
8855 E. Valley Blvd. #B1, Rosemead, CA 91770**

**Product of the USA**

**\* These statements have not been evaluated by Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.**

## Supplement Facts

Serving Size 3 capsules (1.5 g)

Servings per box 30

Amount per Serving	% Daily Value*
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**Calories, Total 5**

<b>Total Carbohydrate</b> 0 g	0%
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### Proprietary Blend (1.5 g)

Mother-of-Pearl ( <i>Pteria margaritifera</i> ) shell (Zhen Zhu Mu)	†
Gecko ( <i>Gekko gekko</i> ) lizard (Ge Jie)	†
Dogwood ( <i>Cornus officinalis</i> ) fruit (Shan Zhu Yu)	†
Chinese Yam ( <i>Dioscorea opposita</i> ) rhizome (Shan Yao)	†
Prepared Rehmannia ( <i>Rehmannia glutinosa</i> ) root (Shu Di Huang)	†
Wolfberry ( <i>Lycium chinense</i> ) fruit (Gou Qi Zi)	†
Dodder ( <i>Cuscuta chinensis</i> ) seed (Tu Si Zi)	†
Chinese angelica ( <i>Angelica sinensis</i> ) root (Dang Gui)†	†
Cinnamon ( <i>Cinnamomum cassia</i> ) bark (Rou Gui)	†
Prepared Aconite ( <i>Aconitum carmichaeli</i> ) root (Fu Zi)	†
Polygala ( <i>Polygala tenuifolia</i> ) root (Yuan Zhi)	†
Ginseng ( <i>Panax ginseng</i> ) root (Ren Shen)	†
Psoralea ( <i>Psoralea corylifolia</i> ) fruit (Bu Gu Zhi)	†
Astragalus ( <i>Astragalus membranaceus</i> ) root (Huang Qi)	†
Eucommia ( <i>Eucommia ulmoides</i> ) bark (Du Zhong)	†
Hoelen ( <i>Poria cocos</i> ) sclerotium (Fu Shen)	†

\*Percent Daily Values are based on a 2,000 calorie diet

† Daily Value not established

Label No.: 1081904

Client No.: C07

Product: Zhen Ge Jiang Tang Dan Capsules (90 x 500 mg)